

2. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

Accredited laboratory is a DNA laboratory that has received formal recognition that it is competent and meets or exceeds a list of standards, including the FBI Director's Quality Assurance Standards, to perform specific tests by a nonprofit professional association of persons actively involved in forensic science that is nationally recognized within the forensic community in accordance with the provisions of the Federal DNA Identification Act (42 U.S.C. § 14132) or subsequent laws.

Accuracy is the degree of conformity of a measured quantity to its actual (true) value.

Administrative review is an evaluation of the report (if applicable) and supporting documentation for consistency with laboratory policies and for editorial correctness.

Analytical documentation is the documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photos and other documentation generated which are used to support the analyst's conclusions.

Analytical procedure is an orderly step-by-step process designed to ensure operational uniformity and to minimize analytical drift.

Analyst/Criminalist is an employee that has successfully completed the laboratory's training requirements for casework sample analysis, passed a competency test, and entered into a proficiency testing program according to these standards. This individual conducts and/or directs the analysis of forensic samples, interprets data, and reaches conclusions.

ANAB is the ANSI-ASQ National Accreditation Board.

Audit is an inspection used to evaluate, confirm, or verify activity related to quality.

Biochemistry is the study of the nature of biologically important molecules in living systems, DNA replication and protein synthesis, and the quantitative and qualitative aspects of cellular metabolism.

Calibration is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.

CODIS is the Combined DNA Index System administered by the FBI. CODIS links DNA evidence obtained from crime scenes, thereby identifying serial criminals. CODIS also compares crime scene evidence to DNA profiles from arrestees and convicted offenders, thereby providing investigators with the identity of the putative perpetrator. In addition, CODIS contains profiles from volunteers, missing persons, unidentified human remains and relatives of missing persons. There are three levels of

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CODIS: the Local DNA Index System (LDIS), used by individual laboratories; the State DNA Index System (SDIS), used at the state level to serve as a state's DNA database containing DNA profiles from LDIS laboratories; and the National DNA Index System (NDIS), managed by the FBI as the nation's DNA database containing all DNA profiles uploaded by participating states.

CODIS Administrator/CODIS Manager is the individual responsible for administration and security of the laboratory's CODIS at the local (casework), state and/or federal level.

CODIS review is an evaluation of notes, data, controls, internal lane standards, allelic ladders, and other documents to ensure DNA profile eligibility prior to uploading or searching a profile in SDIS.

CODIS reviewer is an employee who is a current or previously qualified analyst in the technology and platform being reviewed that performs a CODIS review of, and is not an author of, the applicable case package.

Competency test is a test intended to establish that a trainee has met established minimum standards of skills and knowledge and is thus eligible for advancement, certification, or other official acknowledgement of achievement.

Contamination is the unintentional introduction of exogenous DNA into a DNA sample or PCR reaction.

Continuing education are educational activities (such as classes, lecture series, conferences, seminars, or short courses) that are offered by recognized organizations or individuals that brings participants up to date in their relevant area of competency.

Coursework is an academic class officially recognized and taught through a college or university program in which the participating student successfully completed and received one or more credit hours for the class.

Critical equipment or instruments are those requiring calibration prior to use and periodically thereafter.

Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use on evidentiary samples in order to prevent unnecessary loss of sample.

Developmental validation is the demonstration of the accuracy, precision, and reproducibility of a procedure by a manufacturer, technical organization, academic institution, government laboratory, or other party.

DNA type (also known as a DNA profile) is the genetic constitution of an individual at defined locations (also known as loci) in the DNA. A DNA type derived from nuclear DNA typically consists of

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one or two alleles at several loci (e.g. short tandem repeat loci). The DNA type derived from mitochondrial DNA is described in relation to the revised Cambridge Reference Sequence (Nature Genetics 1999, 23, 147).

Employee is a person: (1) in the service of the applicable federal, state or local government, subject to the terms, conditions and rules of federal / state / local employment and eligible for the federal /state / local benefits of service such as participating in the federal / state / local retirement system or (2) formerly in the service of a federal, state, or local government who returns to service in the agency on a part time or temporary basis but is not eligible for federal /state / local benefits of service.

Expert System is a software program or set of software programs that interprets the data generated from a DNA analysis instrument platform in accordance with laboratory defined quality assurance rules and accurately identifies the data that does and does not satisfy such rules.

FBI is the Federal Bureau of Investigation, the Federal agency authorized by the DNA Identification Act of 1994 to issue quality assurance standards governing forensic DNA testing laboratories and to establish and administer the National DNA Index System (NDIS).

Forensic DNA analysis is the process of identification and evaluation of biological evidence in criminal matters using DNA technologies.

Forensic sample is a biological sample originating from and associated with a crime scene. For example, a sample associated with a crime scene may include a sample that has been carried away from the crime scene.

Genetics is the study of inherited traits, genotype/phenotype relationships, and population/species differences in allele and genotype frequencies.

Guidelines are a set of general principles used to provide direction and parameters for decision making.

Integral component is that portion of an academic course that is so significant and necessary to the understanding of the subject matter as a whole, that the course would be considered incomplete without it.

Internal validation is the in-house demonstration of the reliability and limitation of the procedure.

Known samples are biological material whose identity or type is established.

Laboratory is a facility: (1) employing at least two full-time DNA analysts; and (2) having and maintaining the capability to perform the DNA analysis of forensic and/or known samples at that facility.

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Laboratory support personnel (or equivalent role, position, or title as designated by the Laboratory Director) are employee(s) who perform laboratory duties exclusive of analytical techniques on forensic or database samples.

Methodology is used to describe the analytical processes and procedures used to support a DNA typing technology: for example, extraction methods – manual, automated; quantitation – slot blot, fluorometry, real-time.

Molecular biology is the study of the theories, methods, and techniques used in the analysis of gene structure, organization, and function.

Multi-laboratory system is used to describe an organization that has more than one laboratory performing forensic DNA analysis.

Multiplex system is a test providing for simultaneous amplification of multiple loci that is either prepared commercially or by a laboratory.

Negative amplification control is used to detect DNA contamination of the amplification reagents. This control consists of only amplification reagents without the addition of template DNA.

NIST is the National Institute of Standards and Technology.

On-site visit is a scheduled or unscheduled visit by one or more representatives of the outsourcing laboratory to the vendor laboratory work site performed as a component of the outsourcing laboratory's obligation to verify the integrity of the results received from the vendor laboratory. An on-site visit may, or may not, include the performance of a laboratory audit for compliance with these Quality Assurance Standards (QAS).

Outsourcing is the utilization of a vendor laboratory to provide DNA services in which the originating laboratory retains ownership of the DNA data for entry into CODIS. Outsourcing does not require the existence of a contractual agreement or the exchange of funds.

Ownership occurs when any of the following criteria are applicable:

- (1) the originating laboratory will use any samples, extracts or any materials from the vendor laboratory for the purposes of forensic testing (i.e. a vendor laboratory prepares an extract that will be analyzed by the originating laboratory);
- (2) the originating laboratory will interpret the data generated by the vendor laboratory;
- (3) the originating laboratory will issue a report on the results of the analysis; or
- (4) the originating laboratory will enter a DNA profile into CODIS from data generated by the vendor laboratory.

Performance check is a quality assurance measure to assess the functionality of laboratory instruments and equipment that affect the accuracy and/or validity of forensic sample analysis.

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Platform is the type of analytical system utilized to generate DNA profiles such as capillary electrophoresis, real-time gel, and end-point gel instruments or systems.

Polymerase Chain Reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles which consist of the following:

- (1) denaturation of the template;
- (2) annealing of primers to complementary sequences at an empirically determined temperature;
- (3) extension of the bound primers by a DNA polymerase.

Positive amplification control is an analytical control sample that is used to determine if the PCR performed properly. This control consists of the amplification reagents and a known DNA sample.

Precision characterizes the degree of mutual agreement among a series of individual measurements, values, and / or results.

Procedure (protocol, SOP or other equivalent) is an established practice to be followed in performing a specified task or under specific circumstances.

Proficiency testing is a quality assurance measure used to monitor performance and identify areas in which improvement may be needed. Proficiency tests may be classified as:

- (1) An internal proficiency test is administered by the laboratory undergoing the test.
- (2) An external proficiency test, which may be open or blind, is a test obtained from an approved proficiency test provider.

Qualified auditor is an individual who has successfully completed the FBI DNA Auditor's training course.

Quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

Quantitative PCR is a method of determining the concentration of DNA in a sample by use of the polymerase chain reaction.

Reagent blank control is an analytical control sample that contains no template DNA and is used to monitor contamination from extraction to final fragment or sequence analysis. This control is treated the same as, and parallel to, the forensic and or reference samples being analyzed.

Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body.

Reproducibility is the ability to obtain the same result when the test or experiment is repeated.

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Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

Second agency is an entity or organization external to and independent of the laboratory.

Semi-annual is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year and where the interval between the two events is at least four months and not more than eight months.

Service is the performance of those adjustments or procedures specified which are to be performed by the user, manufacturer or other service personnel in order to ensure the intended performance of instruments and equipment.

Technical Leader (or equivalent role, position, or title as designated by the Laboratory Director) is an employee who is accountable for the technical operations of the laboratory and who is authorized to stop or suspend laboratory operations.

Technical review is an evaluation of reports, notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusions.

Technical reviewer is an employee who is a current or previously qualified analyst in the technology and platform being reviewed that performs a technical review of, and is not an author of, the applicable report or its contents.

Technician (or equivalent role, position, or title as designated by the Laboratory Director) is an employee who performs analytical techniques on forensic samples under the supervision of a qualified analyst. Technicians do not interpret data, reach conclusions on typing results, or prepare final reports.

Technology is used to describe the type of forensic DNA analysis performed that has required the successful completion of validation in the laboratory, such as RFLP, STR, Y-STR, or mitochondrial DNA.

Test kit is a pre-assembled set of reagents that allows the user to conduct a specific DNA amplification.

Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

Underlying scientific principle is a rule concerning a natural phenomenon or function that is a part of the basis used to proceed to more detailed scientific functions.

Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes the following:

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(1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples.

(2) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

Vendor laboratory is a governmental or private laboratory that provides DNA analysis services to another laboratory or agency and does not take ownership of the DNA data for purposes of entry into CODIS.

Work product is the material that is generated as a function of analysis, such as DNA extracts, amplified product and amplification tubes or plates. The Primary Examination Section will sometimes perform the initial processing (batching) of items prior to their being transferred to the DNA Section for further processing. Typically this initial processing will consist of collecting swabs or removing cuttings from original evidence items that may contain biological material or cutting previously collected swabs. This process differs from transferring secondary evidence items to DNA in that the microtubes containing these swabs or cuttings are considered a work product of the DNA Section rather than evidentiary subsets of the original evidence item.

Working days are defined as the days that the laboratory is open.

WCSO is the Washoe County Sheriff's Office.

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